

Message

From: Shams, Dahnish [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7037E39BB6341C8850BCDC61BF9D65A-SHAMS, DAHN]
Sent: 7/30/2020 3:19:36 PM
To: Thayer, Kris [thayer.kris@epa.gov]; Soto, Vicki [Soto.Vicki@epa.gov]
Subject: RE: Inside TSCA - Chloroprene

Understood!

- Dahnish

Chemical and Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Thayer, Kris <thayer.kris@epa.gov>
Sent: Thursday, July 30, 2020 11:19 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Soto, Vicki <Soto.Vicki@epa.gov>
Subject: RE: Inside TSCA - Chloroprene

I'd say make more prominent and findable

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Thursday, July 30, 2020 11:17 AM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: Inside TSCA - Chloroprene

Checking! Its listed as pending. Should I add it to the Recent additions? We were trying to keep some separation from the IRIS side, but at this point, it might help to make it more prominent.

- Dahnish

Chemical and Pollutant Assessment Division (CPAD)
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From: Soto, Vicki <Soto.Vicki@epa.gov>
Sent: Thursday, July 30, 2020 11:14 AM
To: Thayer, Kris <thayer.kris@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: Inside TSCA - Chloroprene

Dahnish can you check with Amparo to see when they are going to make the documents public?

From: Thayer, Kris <thayer.kris@epa.gov>
Sent: Thursday, July 30, 2020 11:10 AM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: FW: Inside TSCA - Chloroprene

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Thursday, July 30, 2020 11:09 AM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: Inside TSCA - Chloroprene

This article says the chloroprene documents aren't available - is that an error?

I looked at the IRIS website and its hard to find anything about the chloroprene peer review, etc. Can this be added to at least the Recent Additions list? To the rotating headline?

Thanks John

From: Soto, Vicki <Soto.Vicki@epa.gov>
Sent: Thursday, July 30, 2020 9:14 AM
To: Thayer, Kris <thayer.kris@epa.gov>; Avery, James <Avery.James@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Persad, Amanda <Persad.Amanda@epa.gov>
Subject: Inside TSCA - Chloroprene

EPA Readies For Landmark Chloroprene Review That Could Ease IRIS Values

July 29, 2020

More than two years after rejecting an industry data quality request to revise a controversial risk analysis for the synthetic rubber chemical chloroprene, EPA is preparing for an unprecedented peer review of industry-funded modeling and related analyses which could lead the agency to revise the Integrated Risk Information System (IRIS) assessment.

EPA announced in a [July 24 Federal Register notice](#) that it is releasing for public comment "a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance," in advance of a pending external peer review.

EPA's peer review contractor, Versar, is also collecting comments on its pool of 19 peer review candidates.

While EPA announced a 30-day comment period that is scheduled to close on Aug. 24, the model documents have yet to be made available in the electronic docket.

The peer review -- and any rollback or revision of the IRIS risk values that may result -- could also set a precedent for any future requests for correction (RFC) to IRIS assessments or other programs under the Data Quality Act (DQA), a Clinton-era law that allows private parties to petition agencies to "correct" actions but which federal courts have held is unenforceable.

While the current case stems from an RFC filed by Denka Performance Elastomers seeking to revise EPA's IRIS values for chloroprene, the American Chemistry Council [has similarly petitioned](#) EPA to scale back conservative risk values that IRIS adopted for ethylene oxide, the sterilizing agent.

In January 2018, [EPA rejected](#) Denka's RFC asking the agency to revise its 2010 IRIS assessment of the human health risks of chloroprene.

Denka's RFC was filed shortly after a critical House science committee hearing on the IRIS program in 2017 where GOP lawmakers featured the chloroprene assessment as an example of the program's conservative risk values that were driving strict regulatory actions.

GOP lawmakers later urged EPA to create [a special mechanism](#) by which the agency can "correct" IRIS analyses.

In the case of chloroprene, the IRIS assessment had proven controversial because, when coupled with air pollution modeling, it had driven strict emissions controls on the company's plant in LaPlace, LA.

EPA based its rejection of the RFC on a systematic review that IRIS staff conducted of studies published on chloroprene between the 2010 publication of the IRIS assessment and the 2017 systematic review, a structured and documented process for transparent literature review and evaluation of the available information, in which staff concluded that no information published to that point materially changed the outcome of the IRIS assessment.

In particular, the IRIS staff concluded that seven new chloroprene studies evaluated "represent novel approaches to analyzing existing epidemiologic, toxicological, and toxicokinetic data available for chloroprene. However . . . it is the opinion of the EPA that these studies do not present sufficient evidence or provide adequate rationale for re-evaluating the entire chloroprene toxicity database."

Request For Reconsideration

But after Denka in July 2018 submitted [a request for reconsideration \(RFR\)](#) of EPA's denial, top EPA risk assessors reached an agreement with the company's consultants to analyze and potentially advance to peer review a new PBPK model that could be used to

revise the agency's controversial 2010 assessment. Such models are generally used to project absorption, distribution, metabolism and excretion (ADME) of synthetic or natural chemical substances in humans and other animal species in risk analyses. The agreement followed a July 2018 meeting between IRIS leaders and Denka's consultants at Ramboll Environ, and Louisiana Department of Environmental Quality (LDEQ) officials.

After the meeting, an EPA source said that Denka's consultants recognized after reading EPA's denial of the 2017 RFC "an opportunity to address one of the critical questions -- the ability to use a PBPK model." And so Denka and Ramboll "proposed to develop a PBPK model . . . they're in the process of developing it." At the time, the source said that "if the model comes in and it's of good quality," the agency will have it externally peer-reviewed.

In a [July 2018 letter](#) after the meeting, Denka thanked IRIS leadership for "the opportunity to present the findings from our updated PBPK model and sensitivity analyses" and also outlined the company's understanding of its agreement with the agency.

"We are prepared to provide EPA with a working PBPK model with full documentation that will allow EPA to use the model and perform the necessary internal and external peer review. . . . We look forward to providing EPA with all the necessary support to facilitate the entire process. We were pleased to hear that EPA intends to give high priority to the PBPK model evaluation and we look forward to receiving an updated timeline for the evaluation process."

Once peer-reviewed, the model could be used to update EPA's 2010 IRIS assessment of chloroprene. Denka and its consultants argue the IRIS assessment contains too strict a cancer risk estimate, driving an emissions level the company said it is unable to meet even after spending more than \$30 million to apply new emissions control technologies to its facility.

Concerns with the Denka plant originated with EPA's 2015 release of its 2011 National Air Toxics Assessment (NATA) data showing high levels near the plant of chloroprene, which it categorized as a likely carcinogen, combined with the 2010 IRIS assessment.

EPA and LDEQ are using NATA to target the plant's emissions - a novel use of the air toxics data to support specific compliance action rather than broader strategic efforts.

The IRIS assessment classified chloroprene as a likely human carcinogen and sets an inhalation unit risk (IUR) estimate for cancer potency of 5×10^{-4} per microgram per cubic meter of air ($\mu\text{g}/\text{m}^3$)⁻¹ when inhaled daily over a lifetime. This IUR, together with the NATA data, is the basis for the enforcement effort to reduce the plant's emissions to 0.2 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$).

'Withdraw And Correct'

In its first appeal to EPA in June 2017, Denka filed the RFC along with a letter from its president and CEO, Koki Tabuchi, who formally petitioned to "withdraw and correct" what he considered errors in EPA's 2010 assessment. Tabuchi in the letter blamed the IRIS assessment for enforcement actions from state and federal officials that he wrote could force a shutdown of the facility, the only neoprene production facility in the U.S.

EPA's recent *FR* notice explains that EPA is preparing for Versar to peer review the PBPK model, which Ramboll completed earlier this year, as well as a "Supplemental Analysis of Metabolite Clearance" that EPA conducted earlier this year. The peer review will "help to inform future decisions regarding the RFR," the notice states.

The notice explains that Versar plans to convene a panel of 9 expert peer reviewers after considering public comments on the candidates and screening them for conflict of interest consistent with EPA's peer review handbook. The panel's meeting information will be released at least 30 days in advance of the meeting.

The notice asks for comments on the 19 peer-review candidates to be sent directly to Versar. Among the candidates are Ken Portier, the outgoing chairman of EPA's Science Advisory Committee on Chemicals (SACC); Jim Bruckner, also a member of SACC and a toxicology professor at the University of Georgia; and Annie Lumen, a modeling expert with the Food and Drug Administration. -- *Maria Hegstad* (mhegstad@iwpnews.com)

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